K093721

FEB 19 2010

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter Information

Company:.....3M ESPE AG

Street:.....ESPE Platz

ZIP-Code, City:.....D-82229 Seefeld

Federal State: .....Bavaria

Country: .....Germany

Establishment Registration Number 9611385

Official Correspondent: .....Dr. Desi W. Soegiarto,

.....Regulatory Affairs Specialist

Phone: 011-49-8152-700 1169

Fax: 011-49-8152-700 1869

E-mail:.....desi.soegiarto@mmm.com

Date:.....February 17, 2010

Name of Device

Proprietary Name:.....CoSP2

Common Name: .....Retraction paste

Classification Name:.....Unclassified

Product code.....MVL

Predicate Devices

Expasyl.....K050180
by Produits Dentaires Pierre Rolland

Hemostasyl Paste K082116
by Produits Dentaires Pierre Rolland

Description for the Premarket Notification

CoSP2, manufactured by 3M ESPE, is a retraction paste for the displacement of marginal gingiva and to provide for a dry sulcus. Any suitable, commonly available dispensers, e.g., the Capsule Applicator, manufactured for 3M ESPE, can be used for application of the retraction paste. The paste is applied directly from the retraction capsule into the sulcus. A CoSP2 retraction capsule may not be used on more than one patient.

Predicate devices to which CoSP2 has been compared are Expasyl by Produits Dentaires Pierre Rolland for Kerr (K050180) and Hemostasyl Paste by Produits Dentaires Pierre Rolland (K082116).

Like its predicate devices, CoSP2 has been design as a pasty alternative to the most common retraction devices which are cords.
Like its predicate devices, CoSP2 is a retraction paste containing aluminum chloride. It is known that aluminum chloride constrics or occludes blood vessels, causing denaturation, producing a physical meshwork (in contrast to epinephrine which is a pharmacological active substance that causes decreasing blood pressure).

CoSP2 is intended to be used for all indications for displacement of the marginal gingiva and to provide for a dry sulcus when the periodontium is healthy, such as:

Taking impressions, either with impression material or as digital impression
Preparation of temporary casts
Preparation of Class II and V fillings

The intended use of CoSP is comparable the area of the intended use of the predicate devices of CoSP2.

In this 510(k) premarket notification chemical composition, performance data (e.g. extrusion force, flow resistance, and rinsing time), and indications for use of CoSP2 habe been compared to its predicate devices.
The comparison for chemistry, performance data and indications for use shows that CoSP2 is substantially equivalent to the predicate devices.

To provide evidence for safety biocompatibility testing was carried out. The results show that CoSP2 is a safe device.

In summary, it can be concluded that safety and effectiveness requirements for CoSP2 are completely met.

Indications for use:

All indications for displacement of the marginal gingiva and to provide for a dry sulcus when the periodontium is healthy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Dr. Desi W. Soegiarto
Regulatory Affairs Specialist
3M ESPE AG
Dental Products
ESPE Platz
D-82229 Seefeld
GERMANY

FEB 19 2010

Re: K093721
Trade/Device Name: CoSP2
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MVL
Dated: November 27, 2009
Received: December 2, 2009

Dear Dr. Soegiarto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093721

Device Name: CoSP2

Indications For Use: All indications for displacement of the marginal gingiva and to provide for a dry sulcus when the periodontium is healthy.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

RSBetz DDS for Dr. K.P. Mulay

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093721